UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Linda Deluise

From: Kevin Sweeney, Senior Entomologist

Date: May 29, 2012

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 395185
Decision no.: 455576
Submission no: 904194
Action code: R350
Product Name: YT-1601 Dog Tag
EPA Reg. No or File Symbol: 39039-14
Formulation Type: RTU impregnated dog tag
Ingredients statement from the label with PC codes included: 10% zeta-cypermethrin (PC code: 129064) and 20% piperonyl butoxide (PC code: 067501)
Application rate(s) of product: 1 dog tag per dog; 4 grams tag for dogs weighing 14-29 lbs; 6 grams for dogs weighing 29 to 55 lbs. and 8 grams for dogs weighing more than 55 lbs.
Use Pattern: residual slow release dog tag attached to the collar
OCSPP Guidelines 810.3300

I. Action Requested: Review four efficacy studies submitted in support of new label claims and expansion of use pattern to include larger dogs.

II. Background: The registrant submitted four new studies to support the expansion of the labeled use pattern to include larger dogs. The original registration had claims for control of fleas for up to three months and brown dog ticks for up to one month. The subject amendment requests: control of fleas up to four months; control of brown dog ticks up to four months; control of Lone Star ticks for up to four months, and aids in control of American dog ticks for up to four months. The presently registered product is applied as a 4 g tag to the dog collar for dogs weighing 14 to 29 lbs. The subject amendment proposes application of a 6 g tag to dogs weighing 29 to 55 lbs and an 8 g tag to dogs weighing over 55 lbs. The registrant claims that the current database for companion animal safety supports the use on larger dogs.

III. MRID Reviews:

MRID 48609701. Hair, J.A. 2010. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks infesting Dogs. Nu-Era Farms, Stillwater, OK

This was a non-GLP study. The primary review of the study was conducted by the EPA contractor and is attached for your information and the file.

Summary: The study was conducted with dogs weighing 65-115 lbs. An 8 g tag was applied to each dog. There were an equal number of treated (6) and untreated dogs (6). Dogs were infested with all two tick species (brown dog tick and American dog tick) and cat fleas once per week or two weeks for up to 174 days.
Conclusion: The study is acceptable. The study results support a four month control claim for 65-115 lbs dogs with the 8 g tag against fleas and the brown dog tick. For American dog tick, the product was efficacious one month. After one month, efficacy ranged from 72-87% against American dog ticks.

MRID 48609702. Hair, J.A. 2011. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks infesting Dogs. Nu-Era Farms, Stillwater, OK

This was a non-GLP study. The primary review of the study was conducted by the EPA contractor and is attached for your information and the file.

Summary: Twelve dogs ranging in weight from 16-27 lbs were used in this study. A 4 g medallion was applied to each dog. Six dogs were allocated to the untreated control and six dogs were allocated to the treatments. Dogs were infested with cat fleas, adult brown dog ticks and adult American dog ticks.

Conclusion: The study is acceptable. When the 4 g tag was applied to dogs weighing 16-27 lbs the study results showed that: the product achieved four weeks control against fleas and three months claim against brown dog ticks. American dog tick efficacy failed earlier than one month.

MRID 48609703. Arends, J. J. 2010. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks infesting Dogs. S & J Farms, Willow Springs, NC

This was a non-GLP study. The primary review of the study was conducted by the EPA contractor and is attached for your information and the file.

Summary: This study was done with an 8 g tag in kennels and exercise areas that were naturally infested with cat fleas, brown dog ticks, Lone Star ticks and American dog ticks. The exercise area was approximately six acres. Six dogs were allocated to each of the treatments, which consisted of the subject product (YT-1601), an untreated control and an 8% abamectin/20% PBO tag (YT-2508). Dog weights ranged from 44.2 lbs to 77.35 lbs.

Flea and tick counts were conducted more often (weekly) at the beginning of the study and less often as the study progressed. Treated dogs were compared to control dogs to determine treatment success for up to 135 days. The natural infestation was not characterized in terms of density and distribution of ticks or fleas. Tick and flea infestation per animal were not reported.

Conclusion: The study is partially acceptable and supports claims of control for the 8 g tag as discussed below. The study supports flea control for up to 3 months. The brown dog data are acceptable for up to one month because the control animals exhibited so few ticks after that time (about 1 per dog). Lone Star tick control claims are supported through 3 months. The product was effective against the American dog tick for 2 months.

MRID 48609704. Hair, J.A. 2011. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks infesting Dogs. Nu-Era Farms, Stillwater, OK

This was a non-GLP study. The primary review of the study was conducted by the EPA contractor and is attached for your information and the file.

Summary: A cattle ear tag (EPA Reg. No. 39039-4) containing the same percentages of active ingredients was tested. One half of the dog tags were formed by cutting them out of a cattle ear tag (A). The other half was remolded from the cattle ear tag (B). The sponsor claimed that these cut-outs were equivalent to the label rate of the subject product. An analysis or the formulation of the cattle ear tag was not submitted. Dogs weighing 16.7 to 29 lbs were treated with a 4 gram tag from either source A or B. There were a total of 18 dogs with 6 allocated to each treatment group including the controls. Dogs were infested with cat fleas and brown dog ticks.

Conclusion: The study is acceptable. The results indicate that the (B) tags were effective against fleas for 4 weeks while the (A) tags were effective for 8 weeks. Results for brown dog ticks showed that the (A) tags were ineffective while the (B) tags were effective for 113 days.

Entomologist's Comments and Recommendations:

1. Add a re-application interval or state product longevity as 4 months.

2. The following claims are acceptable:

"Controls fleas for up to 4 months."
"Controls brown dog ticks for up to 4 months."
"Aids in control of American dog tick for up to 4 months."

3. Change the remaining claims:

"Controls Lone Star ticks for up to 3 months" to "Aids in control of Lone Star ticks for up to 4 months."

"For application to dogs weighing 14-29 lbs. (4 gram medallion)" to "For application to dogs weighing 14-29 lbs. (4 grams medallion)"

"For application to dogs weighing over 29 to 55 lbs. (6 gram medallion)" to "For application to dogs weighing 30 to 55 lbs (6 grams medallion).

"For application to dogs weighing over 55 lbs. (8 gram medallion)" to "For application to dogs weighing 56 lbs. or greater (8 grams medallion)"

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 486097-03. Arends, J.J. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. November 11, 2010.

Treatments to Control Pests of Humans and Pets (OCSPP 810.3300)

Product Name: YT-1601 Dog Tag
EPA Reg. No. or File Symbol: 39039-14
Decision number: 455575
DP number: 395185

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-53

Primary Reviewer:
Claudia Troxel, Ph.D.

Signature: Claudia M. Troxel
Date: JAN 25 2012

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Dennis M. Opresko, Ph.D.

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Robert H. Ross, M.S. Program Manager

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Date: JAN 25 2012

Quality Assurance:
Jennifer Goldberg, B.S.

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Date: JAN 25 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3300]
MRID:	486097-03. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. Arends, J. J. 2010.
DP BARCODE:	395185
DECISION NO:	455575
SUBMISSION NO:	904194
SPONSOR:	Y-TEX Corporation, 1825 Big Horn Ave, Cody, WY 82414
TESTING FACILITY:	S&J Farms, 2340 Sanders Rd., Willow Springs, NC 27592
STUDY DIRECTOR:	James J. Arends, Ph.D.
SUBMITTER:	Joe D. Kellerby, Vice President – Specialty Products, Y-TEX Corporation
STUDY COMPLETED:	29/08/2010
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	"This study does not report data that is required to be generated under the Environmental Protection Agency's Good Laboratory Practice (GLP) Standards, 40 CFR Part 160. For this reason, this study was not conduced under GLP standards. However, every precaution was taken to assure the data presented in the Final Report was accurate and complete."
TEST MATERIAL: [As noted on label]	PRODUCT NAME: YT-1601 Dog Tag EPA REGISTRATION NUMBER OR FILE SYMBOL: 39039-14 ACTIVE INGREDIENT NAME: Zetacypermethrin, S-enantiomer CHEMICAL NAME: S-Cyano(3-phenoxyphenyl)methyl

	(+-)cis/trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate A.I. %: 10% PC CODE: 129064 CAS NO.: 52315-07-8 ACTIVE INGREDIENT NAME: Piperonyl butoxide CHEMICAL NAME: (butylcarbityl)(6-propylpiperonyl)ether A.I. %: 20% PC CODE: 067501 CAS NO.: 51-03-6 FORMULATION TYPE: Collar attached medallion PRODUCT APPLICATION RATE(S): ACTIVE INGREDIENT APPLICATION RATE(S):
PROPOSED LABEL MARKETING CLAIMS:	Controls fleas for up to four months, Controls Brown Dog ticks for up to four months, Controls Lone Star ticks for up to three months, aids in control of American Dog ticks for up to four months, for application to dogs weighing 14-19 pounds (4 g medallion label), for application to dogs weighting over 55 pounds (8 g medallion label)

STUDY REVIEW

Purpose: The objectives of this study were to determine the efficacy of candidate insecticide dog tag formulations for control of fleas and ticks infesting dogs weighing 20-35 kg, to determine the residual protection achieved from the treatments for tick control over time, and to determine whether any adverse reactions occur from the treatments.

MATERIALS AND METHODS

Test Location S&J Farms, Willow Springs, NC.

Test Material(s):

YT-1601 comprised of 10% Zetacypermethrin and 20% Piperonyl Butoxide Tech. (PBO) in an 8-gram tag on a collar; equivalent to label rate;
YT-2508 comprised of 8% Abamectin and 20% PBO;
Untreated control

Only results from the testing of YT-1601 are discussed.

Test Species Name, Life Stage, Sex and Age: Lone Star ticks (*Amblyomma americanum*), American Dog Ticks (*Dermacentor variabilis*), Brown Dog Ticks (*Rhipicephalus sanguineus*), and fleas (*Ctenocephalides felis*).

Experimental animal: dog (*Canis familiaris*); English X American Fox Hounds, mixed ages, 9 males and 9 females; 20 to 35 kg.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Dogs were maintained under standard kennel management with one kennel run for each treatment group. Runs were 20 x 30 feet with water provided ad. lib. All animals were allowed access as a group for 2 to 3 hours a day to a 6 acre exercise area comprised of open grass as well as wooded areas (50/50).

All infestation of fleas and ticks were from natural exposure from pre-existing populations. The Brown Dog ticks were from an infestation in the kennel runs and exposure was for the entire study. The adult Brown Dog ticks found hosts; therefore, the population naturally declined over the course of the study. The Lone Star ticks and American Dog ticks were naturally occurring in the outdoor exercise area and exposure occurred after day 14 through the end of the study.

List the treatments including untreated control: The 8-gram tag containing 10% Zetacypermethrin and 20% PBO or the 8 gram tag containing 8% Abamectin and 20% PBO was attached to standard nylon collar using a "D" ring. Controls were untreated.

Number of replicates per treatment: 6 dogs/ test group.

Number of individuals per replicate: Variable; evaluated control of naturally occurring infestation of fleas and ticks.

Length of exposure to treatment (time in seconds, minutes or hours): Fleas and Brown Dog ticks were exposed the entire study duration; Lone Star ticks and American Dog ticks were first observed on Day 28, continuing until the end of study.

Were tested specimens transferred to clean containers? Not applicable.

Experimental conditions (state relative humidity, temperature, and photoperiod): Variable; dogs were maintained under standard kennel management but allowed access as a group for 2 to 3 hours a day to an outside exercise area comprised of open grass as well as wooded areas.

Data or endpoints collected/recorded: Ticks were counted on Days 0, 3, 7, 14, 28, 42, 63, 91, and 119. Fleas were counted on the same days as well as on day 135.

Data analysis: Mean flea and tick counts per dog and percent reduction on dogs were tabulated.

RESULTS

Raw data were not included and total flea and tick counts on each specified day were not provided; only mean values per dog were presented.

YT-1601 Dog Tag was 100% effective in controlling fleas starting on Day 3 and continuing up to 91 days. Efficacy dropped to 66% and 31% on Days 119 and 135, respectively. A summary of the data is presented in the following table.

Table 2. Mean fleas/ dog/ sampling day YT-1601

	Day 0	Day 3	Day 7	Day 14	Day 28	Day 42	Day 63	Day 91	Day 119	Day 135
YT-1601	7.67	0.00	0.00	0.00	0.00	0.00	0.00	0.00	9.67	15.83
Control	6.17	6.50	7.83	11.67	11.67	9.33	14.17	24.83	28.17	25.00
% control		100.00	100.00	100.00	100.00	100.00	100.00	100.00	65.68	31.16

The YT-1601 Dog Tag gave 84% control of Brown Dog ticks (*R. sanguineus*) by Day 3 and provided effective control from Day 7 through Day 91, with a mean of only 0.36 ticks per dog per count compared to a mean of 20.83 ticks per dog in the control group. The average weekly percent control of the Brown Dog tick was 95.3% during this period. (NOTE: the brown tick infestation of the control animals dropped substantially from Day 28 to the end of the study). Lone Star ticks and American Dog ticks did not appear on the control group until Day 28 (although American Dog ticks were evident on the treated group at Day 0). Lone Star ticks were effectively controlled on Days 28 to 91 with average weekly percent control of 94.5% before declining to 86.5% by Day 119. American Dog ticks were effectively controlled on Days 28 to 63 with an average of 96.4% control before declining to an average of 82.5% control between Day 91 and Day 119. A summary of the data is presented in the following table.

Table 4. Mean Ticks /dog/Sampling day YT-1601

R. sanguineus	Day 0	Day 3	Day 7	Day 14	Day 28	Day 42	Day 63	Day 91	Day 119
YT-1601	109.67	12.17	1.83	0.00	0.33	0.00	0.00	0.00	0.83
Control	94.33	75.00	53.83	66.83	1.33	1.83	1.00	0.17	1.00
% control		83.78	96.59	100.00	75.00	100.00	100.00	100.00	16.67
A. americanum	Day 0	Day 3	Day 7	Day 14	Day 28	Day 42	Day 63	Day 91	Day 119
YT-1601	0.00	0.00	0.00	0.00	1.17	0.33	1.00	1.17	4.50
Control	0.00	0.00	0.00	0.00	15.67	28.33	23.00	12.33	33.33
% control					92.55	98.82	95.35	90.54	86.50
D. variabilis	Day 0	Day 3	Day 7	Day 14	Day 28	Day 42	Day 63	Day 91	Day 119
YT-1601	9.00	0.00	0.00	0.00	0.00	0.17	0.67	1.00	5.17
Control	0.00	0.00	0.00	0.00	4.50	22.17	18.50	4.83	25.17
% control					100.00	99.25	96.40	79.31	85.71

Study Author's Conclusions

Flea counts for YT-1601 were 0 by Day 3 and remained at 0 for 91 days post treatment. YT-1601 treatment substantially reduced Brown Dog ticks by Day 3 (84%) and exhibited over 95% control by day 7 post treatment. Control of greater than 90% of Lone Star ticks was observed Days 28 to Day 91. American Dog ticks showed a similar trend with control greater than 95% Days 28 to 63.

Because the infestations were from naturally existing populations, the results are more erratic than would be seen if exposure had been from laboratory infestations of controlled quantity and duration. The study does represent a realistic challenge for the test products which demonstrated good control; YT-1601 demonstrated greater than 90% control through day 63 when all tick species are combined.

Reviewer's Conclusions

1. All dogs survived to study termination, and no adverse effects related to treatment were observed.

2. Efficacy was determined by counting the number of fleas and ticks on the dogs on specified days, and calculating the percent control. Abbott's Formula was not used.

3. Despite the low mean number of fleas on the control dogs (average of 6 to 28/dog), it appears that YT-1601 was effective against fleas over Days 3 to 91 with 100% control. Control then declined to 66% and 31% on Days 119 and 135, respectively. The low number of fleas on control dogs is acceptable: guidelines state that there should be a minimum of 5 fleas per dog.

4. Determining the efficacy of YT-1601 against ticks was problematic due to low numbers of ticks on control dogs for long durations of the study. YT-1601 clearly controlled Brown Dog ticks over days 3 to 14, when efficacy ranged from 84 to 100%. It is difficult to determine efficacy for Days 28 to Day 119 because of the low average of ticks on controls (0.17 to 1.83 mean ticks/dog); guidelines state "in general, a minimum of 3 ticks… per dog (controls) are necessary for a valid test."

5. No Lone Star ticks or American Dog ticks were present on any control dogs during Days 0 to 14. YT-1601 controlled for both kinds of ticks when they started to appear on control dogs on Days 28, controlling 87-99% of Lone Star ticks on Days 28 to 119 (the mean number of ticks/control dog ranged from 12 to 33) and 96 to 100% of American Dog ticks on Days 28 to 63 (the mean number of ticks/control dog ranged from 4.5 to 36).

Reviewer's Recommendations

1. The study is acceptable, although relying on infestation of fleas and ticks only from natural exposure to pre-existing populations resulted in insufficient numbers of ticks to adequately evaluate YT-1601 control over the desired duration.

2. The study does not support the addition of fleas to the product label "Controls fleas for up to 4 months;" however, the data do support the control of fleas for the duration of 3 months.

3. The study does not support the addition of Brown Dog Ticks (*Rhipicephalus sanguineus*) to the product label because of an insufficient minimum number of ticks on the control dogs.

4. The study does support the addition of Lone Star ticks (*Amblyomma americanum*) to the product label "Controls Lone Star ticks for up to 3 months."

5. The study does not support the addition of American Dog Ticks (*Dermacentor variabilis*) to the product label "Aids in Control American Dog ticks for up to 4 months;" however, the data do support the claim "aids in the control of American Dog ticks" for the duration of 3 months.

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TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 486097-04. Hair, J.A. The Efficacy of YT-1601 Dog Tag (Zetacypermethrin/PBO) Formulations for the Control of Fleas and Ticks Infesting Dogs. August 18, 2011.

OCSPP 810.3300. Treatments to Control Pests of Humans and Pets

Product Name: YT-1601 Dog Tag
EPA Reg. No. or File Symbol: 39039-14
Decision number: 455575
DP number: 395185

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-53

Primary Reviewer:
Claudia Troxel, Ph.D.

Signature: Claudia M. Troxel
Date: JAN 25 2012

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

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Date: JAN 25 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: JAN 25 2012

Quality Assurance:
Jennifer Goldberg, B.S.

Signature:
Date: JAN 25 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3300]
MRID:	486097-04. The Efficacy of YT-1601 Dog Tag (Zetacypermethrin/PBO) Formulations for the Control of Fleas and Ticks Infesting Dogs. Hair, J.A. 2011.
DP BARCODE:	395185
DECISION NO:	455575
SUBMISSION NO:	904194
SPONSOR:	Y-TEX Corporation, 1825 Big Horn Ave, Cody, WY 82414
TESTING FACILITY:	Nu-Era Farms, 320 N. Range Rd., Stillwater, OK 74075
STUDY DIRECTOR:	J. Alexander Hair, Ph.D.
SUBMITTER:	Joe D. Kellerby, M.S., P.E., Vice President – Specialty Products, Y-TEX Corporation
STUDY COMPLETED:	15/7/2011
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	"Although this study was not conducted to GLP requirements of 40 CFR Part 160, good scientific practices were followed throughout."
TEST MATERIAL: [As noted on label]	PRODUCT NAME: YT-1601 Dog Tag EPA REGISTRATION NUMBER OR FILE SYMBOL: 39039-14 ACTIVE INGREDIENT NAME: Zetacypermethrin, S-enantiomer CHEMICAL NAME: S-Cyano(3-phenoxyphenyl)methyl (+-)cis/trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate A.I. %: 10% PC CODE: 129064

	CAS NO.: 52315-07-8 ACTIVE INGREDIENT NAME: Piperonyl butoxide CHEMICAL NAME: (butylcarbityl)(6-propylpiperonyl)ether A.I. %: 20% PC CODE: 067501 CAS NO.: 51-03-6 FORMULATION TYPE: Collar attached medallion PRODUCT APPLICATION RATE(S): ACTIVE INGREDIENT APPLICATION RATE(S):
PROPOSED LABEL MARKETING CLAIMS:	Controls fleas for up to four months, Controls Brown Dog ticks for up to four months, Controls Lone Star ticks for up to three months, aids in control of American Dog ticks for up to four months, for application to dogs weighing 14-19 pounds (4 g medallion label)

STUDY REVIEW

Purpose: The objectives of this study were to determine the efficacy of candidate insecticide dog tag formulations when molded or cut out of larger tags for control of fleas and ticks infesting dogs, determine the residual protection achieved from the treatments for flea and tick control over time, and determine if there were any adverse reactions to the tags as well as tag retention over time.

MATERIALS AND METHODS

Test Location Nu-Era Farms, Stillwater, OK.

Test Material(s): Two different YT-1601 tags comprised of Zetacypermethrin (10%) and Piperonyl Butoxide Tech. (20%) were tested; both were equivalent to the label rate.

Tag YT-1601A (cut out) 4 gram YT-1601 Dog Tag cut from Python Insecticide Cattle Ear Tags (EPA Reg, No. 39039-4), lot no. EP931002, molded Dec. 12, 2009;

Tag YT-1601B (molded) 4-gram YT-1601 Dog Tag re-molded from Python Insecticide Cattle Ear Tags (EPA Reg. No. 39039-4), lot no. EP931002, re-molded Nov. 30, 2010.

Test Species Name, Life Stage, Sex and Age: Adult Brown Dog ticks (*Rhipicephalus sanguineus*) and adult Cat fleas (*Ctenocephalides felis*).

18 dogs

Experimental animal: purebred beagle (*Canis familiaris*); 3-11 years, 8 males and 8 females; 7.55 to 13.15 kg.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Dogs were housed in indoor pens approximately 3 x 10 x 5 feet high with welded wire walls and concrete floors. Dogs were housed in an environmentally controlled building except from Day 35-59 and 73-97 when they were moved to outdoor, Bermuda

grass-sodded runs where they were held until their return to indoor kennels for flea and tick challenges on days 60/61, days 98/99, and days 111/112. Outdoor runs were equipped with poly-dome type houses and lean-to shelters which offered protection from the elements.

Dogs were assigned to treatments by lottery. Treatment 1 was the cut-out tag, Treatment 2 was the molded tag, and Treatment 3 was the untreated animals. Day 0 was the day on which dogs were treated with YT-1601 Dog Tags. After treatment, the animals were observed at 3, 6, 12, and 24 hours for any adverse events associated with tag application.

Dogs were infested with ticks on Days -1, 4, 11, 18, 32, 60, 70, 98, and 111, and were infested with fleas on Days 1, 5, 12, 19, 33, 61, 71, 99, and 112. Fleas and ticks were counted and removed on Days 2, 6, 13, 20, 34, 62, 72, 100, and 113.

List the treatments including untreated control (express application rate as g/m^2):
4-gram tag containing 10% Zetacypermethrin and 20% Piperonyl Butoxide Tech.;
YT-1601A; Treatment 1: tag was cut out from Python Insecticide Cattle Ear Tags;
YT-1601B; Treatment 2: tag was re-molded from Python Insecticide Cattle Ear Tags
Treatment 3: Controls; only stated that they were "Untreated Controls," not known if a placebo collar was used.

Number of replicates per treatment: 6 dogs/ treatment group .

Number of individuals per replicate: Not stated; number of Cat fleas (*Ctenocephalides felis*) on control dogs ranged from 52-83 per dog (average of 62-74 for the entire control group over the course of the study); number of Brown dog ticks (*Rhipicephalus sanguineus*) on control dogs ranged from 11-39 per dog (average of 15-29 for the entire control group over the course of the study).

Length of exposure to treatment (time in seconds, minutes or hours): Ticks and fleas were removed approximately 48 hours and 24 hours after infestation, respectively; reinfestations occurred up to 113 days.

Were tested specimens transferred to clean containers? No, not applicable.

Experimental conditions (state relative humidity, temperature, and photoperiod):
Dogs were housed in indoor pens in an environmentally controlled building except on Days 35-59 and 73-97 when the dogs were moved to outdoor runs.

Data or endpoints collected/recorded: Ticks and fleas were counted and removed on specified days.

Data analysis: Flea and tick counts and percent reduction on dogs compared to controls were tabulated.

RESULTS

Raw data were not included but total flea and tick counts on each specified day were provided in tabular form. Abbott's formula was not used to calculate the percent efficacy of treatments.

It was noted in the study that dislodgement of tags from the collar D ring occurred. It was assumed that the two halves of the clip spread apart and this allowed the tag to be dislodged. The clip apparently needs to be modified so as not to allow for the opening of the 2 halves that apparently allow for the disconnecting of the tag. This retention issue may account for some of the reduced efficacy seen in the study compared to previous studies with this product. A summary of the dislodgements is presented in the following table.

Table 3. *Tag retention on beagle dogs in Study #OK-11-A wearing nylon collars with attached "D" rings to which tags were affixed. The tag clips were a 2-piece aluminum inverted "J" that overlapped upon closing on the "D" ring.*

Tag Retention/Loss

Dog #	Tag Missing Date	Tag Located?	Replaced Date	Detachment Cause
0741	01 Apr 11	Yes	01 Apr 11	Clip separation
0828	04 Apr 11	Yes	04 Apr 11	Clip separation
0736	07 Apr 11	Yes	07 Apr 11	Clip separation
0766	11 Apr 11	Yes	11 Apr 11	Clip separation
0766	14 Apr 11	Yes	14 Apr 11	Clip separation
0821	20 Apr 11	Yes	20 Apr 11	Collar came off
0759	23 Apr 11	Yes	23 Apr 11	Clip separation
0759	27 Apr 11	Yes	27 Apr 11	Tag chewed
0736	28 Apr 11	Yes	28 Apr 11	Clip separation
0766	01 May 11	No/Yes Relocated 23 Jun 11	23 Jun 11	Clip separation
0712	02 May 11	Yes	02 May 11	Clip separation
0767	05 May 11	Yes	05 May 11	Clip separation
0767	10 May 11	Yes	10 May 11	Clip separation
0759	14 May 11	Yes	14 May 11	Tag torn
0759	16 May 11	Yes	16 May 11	Tag chewed
0759	03 Jun 11	Yes	03 Jun 11	Tag chewed
0759	23 Jun 11	No	N/A	N/A
0766	27 Jun 11	Yes	27 Jun 11	Clip separation
0761	28 Jun 11	Yes	28 Jun 11	Clip separation
0761	13 Jul 11	Yes	13 Jul 11	Clip separation

YT-1601A (cut out) Dog Tag was generally effective in controlling Cat fleas starting on Day 6 and continuing up to day 72, with the percent efficacy ranging from 86% to 98%. Efficacy dropped significantly to only 21 and 45% on Days 100 and 113, respectively.

YT-1601B (molded) Dog Tag was generally effective in controlling Cat fleas. At Day 2 the molded tag produced 89% reduction of fleas and near 100% was seen for 34 days. For the next 38 days, a high degree of control was seen (87-88%) before efficacy became variable at Day 100, dropping to 35 and 72% on Days 100 and 113, respectively.

Comparing the two tags, the YT-1601B (molded) tags gave greater and quicker kill of Cat fleas when compared to the YT-1601A (cut out). From Day 2 to 72, the overall reduction of fleas with the molded tag was 95% compared to 88% for the cut out tag.

A summary of the data is presented in the following table.

Table 1. A comparison of the numbers of cat fleas on beagles treated with either a 4-gram cut-out tag (from 9.5-gram commercial cattle tag, same formulation) or a 4-gram molded Zetacypermethrin/PBO tag to untreated beagles under an indoor/outdoor situation, Nu-Era Farms, Stillwater, OK 74075, Spring 2011. Arithmetic mean percent control is given.

			Flea Counts (*C. felis*)									
Dog #	Tag Weight (grams)	25 Mar 11 Day +2	29 Mar 11 Day +6	05 Apr 11 Day +13	12 Apr 11 Day +20	26 Apr 11 Day +34	24 May 11 Day +62	03 Jun 11 Day +72	01 Jul 11 Day +100*	14 Jul 11 Day +113**
0740	untreated	73	73	69	59	54	63	59	78	78
0738	untreated	66	71	73	67	60	54	61	63	67
0751	untreated	72	69	66	61	65	69	63	69	81
0743	untreated	59	83	71	73	66	70	67	71	69
0742	untreated	63	68	63	69	62	52	54	62	74
0810	untreated	68	82	83	63	67	65	68	81	77
Average		**66.8**	**74.3**	**70.8**	**65.3**	**62.3**	**62.2**	**62.0**	**70.7**	**74.3**
0759	4 (A--cut out)	37	13	7	1	3	12	19	75	72
0828	4 (A--cut out)	3	10	0	0	1	6	13	35	10
0837	4 (A--cut out)	37	13	12	3	2	10	5	71	47
0821	4 (A--cut out)	22	4	0	0	0	5	8	63	41
0761	4 (A--cut out)	27	13	3	2	0	3	0	54	46
0780	4 (A--cut out)	22	11	14	2	3	1	1	37	28
Average		**24.7**	**10.7**	**6.0**	**1.3**	**1.5**	**6.2**	**7.7**	**55.8**	**40.7**
% Control		**63.1**	**85.7**	**91.5**	**98.0**	**97.6**	**90.1**	**87.6**	**21.0**	**45.3**
0736	4 (B--molded)	2	0	0	0	0	4	7	52	5
0741	4 (B--molded)	20	1	0	0	0	6	3	44	12
0752	4 (B--molded)	0	0	2	0	0	0	1	53	41
0767	4 (B--molded)	7	0	0	0	1	12	9	31	31
0712	4 (B--molded)	9	0	0	0	0	9	10	72	29
0766	4 (B--molded)	8	0	0	0	0	19	15	22	9
Average		**7.7**	**0.2**	**0.3**	**0.0**	**0.2**	**8.3**	**7.5**	**45.7**	**21.2**
% Control		**88.5**	**99.8**	**99.5**	**100.0**	**99.7**	**86.6**	**87.9**	**35.4**	**71.5**

*This count was moved from Day 102 to Day 100 as allowed by protocol

**This count was moved from Day 112 to Day 113 as allowed by protocol

YT-1601A (cut out) Dog Tag was only moderately effective in controlling Brown Dog ticks starting on Day 6 and continuing up to day 113, with the percent efficacy ranging from 42% to 89%.

YT-1601B (molded) Dog Tag was variably effective in controlling Brown Dog ticks starting on Day 6 and continuing up to day 113, with the percent efficacy ranging from 75% to 99%.

When compared to the YT-1601A (cut out) Dog Tag, the YT-1601B (molded) Dog Tag gave much better results against Brown Dog ticks. The molded tags were a bit slow to kill established tick infestations (only 42.5% on Day 2) but degree of control quickly rose to 77.8% by Day 6 and then to 96.1% on Day 13. An additional 60 days of excellent control was seen with the molded tag whereas the cut out tag gave fair to good control from Days 13 through Day 34. Though control dropped to 74.6% on Day 100 with the molded tag, control was back up to 98.6% on Day 113. From Day 6 to 113, the overall reduction of ticks with the molded tag was 90% and for the cut out tag was 64%.

A summary of the data is presented in the following table.

Table 2. A comparison of the numbers of brown dog ticks on beagles treated with either a 4-gram cut-out tag (from 9.5-gram commercial cattle tag) or a 4-gram molded Zetacypermethrin/PBO tag to untreated beagles under an indoor/outdoor situation, Nu-Era Farms, Stillwater, OK 74075, Spring 2011. Arithmetic mean percent control is given.

			Tick Counts (*R. sanguineus*)								
Dog #	Tag Weight (grams)	25 Mar 11 Day -2	29 Mar 11 Day +6	05 Apr 11 Day +13	12 Apr 11 Day +20	26 Apr 11 Day +34	24 May 11 Day +62	03 Jun 11 Day +72	01 Jul 11 Day +100*	14 Jul 11 Day +113**
0740	untreated	26	16	21	28	31	35	31	26	35
0738	untreated	17	13	19	21	20	23	24	23	21
0751	untreated	23	11	18	19	17	27	29	31	33
0743	untreated	18	14	24	29	30	33	34	29	28
0742	untreated	18	17	20	25	27	24	26	27	26
0810	untreated	25	19	26	24	21	29	24	39	30
Average		**21.2**	**15.0**	**21.3**	**24.3**	**24.3**	**28.5**	**28.0**	**29.2**	**28.8**
0759	4 (A--cut out)	31	5	5	8	6	13	32	23	17
0828	4 (A--cut out)	22	0	0	1	0	5	2	9	3
0837	4 (A--cut out)	13	6	1	1	0	18	1	10	2
0821	4 (A--cut out)	18	3	4	7	8	11	14	14	17
0761	4 (A--cut out)	26	3	4	5	4	14	20	24	5
0780	4 (A--cut out)	35	31	0	9	10	16	18	14	4
Average		**24.2**	**8.0**	**2.3**	**5.2**	**4.7**	**12.8**	**14.5**	**17.0**	**9.0**
% Control		**-14.2**	**46.7**	**89.1**	**78.8**	**80.8**	**55.0**	**48.2**	**41.7**	**~ 68.8**
0736	4 (B--molded)	3	1	1	0	0	0	0	3	0
0741	4 (B--molded)	13	2	1	0	2	2	1	0	1
0752	4 (B--molded)	11	7	2	7	3	16	5	12	1
0767	4 (B--molded)	9	0	0	1	1	2	1	10	0
0712	4 (B--molded)	16	1	1	0	0	1	2	5	1
0766	4 (B--molded)	21	9	0	1	0	1	0	7	0
Average		**12.2**	**3.3**	**0.8**	**1.5**	**1.0**	**3.7**	**1.5**	**7.4**	**0.4**
% Control		**42.5**	**77.8**	**96.1**	**93.8**	**95.9**	**87.1**	**94.6**	**74.6**	**98.6**

*This count was moved from Day 102 to Day 100 as allowed by protocol.

**This count was moved from Day 112 to Day 113 as allowed by protocol.

Study Author's Conclusions

Data suggest better release features of the 4-gram molded Dog Tag compared to the 4 gram cut out from the 9.5 gram commercial cattle tag. Better control of fleas and ticks was noted when the molded tag was compared to the 4-gram cut out version. Good flea control was seen as early as Day 2 post-treatment and good to excellent control was obtained through Day 72.

Brown Dog tick control with the molded tag was a bit poorer than noted for fleas but after 6 days very good results were noted through Day 72.

Based on these studies, the molded YT-1601 Dog Tag demonstrates good potential for commercialization.

Tag retention was a bit of a problem due to what appeared to be clip (attachment) separation which then allowed the tag to drop from the collar. This assumption was based on the fact that in most cases there was not physical damage noted to the tag and its attachment clip.

Reviewer's Conclusions

1. All dogs survived to study termination, and no adverse effects related to treatment were observed.

2. The percent efficacy of the product was calculated but was not corrected using a modified Abbott's Formula.

3. Efficacy of YT-1601B molded Dog Tags against Cat fleas ranged from 86-100% over Days 2 to 72, dropping significantly at Day 100 to 35%. Efficacy of YT-1601A cut out Dog Tags against Cat fleas ranged from 63-98% efficacy over Days 2 to 72, dropping significantly at Day 100 to 21%. Guidelines state "for fleas, a minimum of 90% control, as compared to the counts on the placebo animals, is required for the duration of testing."

4. YT-1601B (molded) Dog Tag was variably effective in controlling Brown Dog ticks. Control started slowly, being at 43% at Day 2 and increasing to 78% on Day 6. Control was acceptable over Days 13 to 72, ranging from 87-96%, before dropping to 75% at Day 100. YT-1601A (cut out) Dog Tag was less effective in controlling Brown Dog ticks, ranging from 42-89% over Days 6 to 113.

Reviewer's Recommendations

1. The study is acceptable, although the results are questionable due to the separation of the clip which allowed the tag to drop from the collar.

2. The study does not support the addition of fleas to the product label; the data do not support the claim "Controls fleas for up to 4 months" because flea control fell below 90%. — 2 months.

3. The study does not support the addition of Brown Dog ticks to the product label as currently specified; the data do not support the claim "Controls Brown Dog ticks for up to 4 months" for "application to dogs weighing 14-29 pounds (4 gram medallion label)" because efficacy was demonstrated only for 59 days, or 2 months.

Correct.

113 days.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 486097-02. Hair, J.A. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. January 27, 2011.

OCSPP 810.3300. Treatments to Control Pests of Humans and Pets

Product Name: YT-1601 Dog Tag
EPA Reg. No. or File Symbol: 39039-14
Decision number: 455575
DP number: 395185

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-53

Primary Reviewer:
Claudia Troxel, Ph.D.

Signature: Claudia M. Troxel
Date: JAN 25 2012

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature:
Date: JAN 25 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: JAN 25 2012

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JAN 25 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3300]
MRID:	486097-02. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. Hair, J.A. 2011.
DP BARCODE:	395185
DECISION NO:	455575
SUBMISSION NO:	904194
SPONSOR:	Y-TEX Corporation, 1825 Big Horn Ave, Cody, WY 82414
TESTING FACILITY:	Nu-Era Farms, 320 N. Range Rd., Stillwater, OK 74075
STUDY DIRECTOR:	J. Alexander Hair, Ph.D.
SUBMITTER:	Joe D. Kellerby, M.S., P.E., Vice President – Specialty Products, Y-TEX Corporation
STUDY COMPLETED:	05/10/2010
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	"Although this study was not conducted to GLP requirements of 40 CFR Part 160, good scientific practices were followed throughout."
TEST MATERIAL: [As noted on label]	PRODUCT NAME: YT-1601 Dog Tag EPA REGISTRATION NUMBER OR FILE SYMBOL: 39039-14 ACTIVE INGREDIENT NAME: Zetacypermethrin, S-enantiomer CHEMICAL NAME: S-Cyano(3-phenoxyphenyl)methyl (+-)cis/trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate A.I. %: 10% PC CODE: 129064

	CAS NO.: 52315-07-8 ACTIVE INGREDIENT NAME: Piperonyl butoxide CHEMICAL NAME: (butylcarbityl)(6-propylpiperonyl)ether A.I. %: 20% PC CODE: 067501 CAS NO.: 51-03-6 FORMULATION TYPE: Collar attached medallion PRODUCT APPLICATION RATE(S) g/m^2: ACTIVE INGREDIENT APPLICATION RATE(S)g/m^2:
PROPOSED LABEL MARKETING CLAIMS:	Controls fleas for up to four months, Controls Brown Dog ticks for up to four months, aids in control of American Dog ticks for up to four months, for application to dogs weighing 14-19 pounds (4 g medallion label)

STUDY REVIEW

Purpose: The objectives of this study were to determine the efficacy of candidate insecticide dog tag formulations (4 gram size) for control of fleas and ticks infesting dogs weighing 7.3 to 12.25 kg, to determine the residual protection achieved from the treatments for flea and tick control over time, and to determine whether any adverse reactions occurred from the treatments.

MATERIALS AND METHODS

Test Location Nu-Era Farms, Stillwater, OK.

Test Material(s): YT-1601 comprised of Zetacypermethrin (10%) and Piperonyl Butoxide Tech. (20%) in a 4-gram tag on a collar; equivalent to label rate.

Test Species Name, Life Stage, Sex and Age: Adult Brown Dog ticks (*Rhipicephalus sanguineus*), adult American Dog ticks (*Dermacentor variabilis*), and adult Cat fleas (*Ctenocephalides felis*).

Experimental animal: purebred beagle (*Canis familiaris*); 2-5 years, 5 males and 7 females; 7.30 to 12.25 kg.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Dogs were housed in indoor pens approximately 3 x 10 x 6 feet high with welded wire walls and concrete floors. After allocation, dogs were groups by treatment and different treatment groups were separated by physical space. Dogs were infested with approximately 50 Brown Dog ticks on Day -5 to determine that the dogs were suitable hosts. These ticks were counted and removed on Day -3, approximately 48 hours after infestation. It was determined that the dogs were suitable parasite hosts for the trial.

Fleas were infested onto the dog by placing the open top of a container with a known number of fleas on the flank of the animals and holding the container in place until the parasites entered the

hair coat. Flea infestation was evaluated at approximately 24 hours post challenge as outlined in the Schedule of Operations. The hair coat was examined in a methodical manner to count fleas on all portions of the dog including the tail and legs. Fleas were combed from the dogs and counted and disposed of.

Ticks were infested onto the dogs by scattering the unfed ticks onto the hair coat of the dog taking care to avoid the site of treatment and to avoid having a large number of ticks attach in a small area. Ticks were removed and counted on all dogs at approximately 48 hours after challenge as per the Schedule of Operations, with the exception of the tick counts on Days +2 which was approximately 72 hours after challenge due to treatment. Tick counts were performed by pushing the animal's hair against its natural nap so that the skin and any ticks were exposed during the process. All areas of the animals were systematically examined and ticks removed with blunt-point forceps and placed in a dish of alcohol for counting.

Dogs were infested with approximately 50 of each type of tick on Days -1, 4, 7, 11, 18, 32, 46, 60, 74, 88, 102, and 117, and were infested with approximately 100 Cat fleas on Days 1, 5, 12, 19, 33, 47, 61, 75, 89, 103, 118, and 131. Fleas and ticks were counted and removed on Days 2, 6, 13, 20, 34, 48, 62, 76, 90, 104, 119, and 132 (fleas only).

List the treatments including untreated control (express application rate as g/m^2):
The 4-gram tag containing 10% Zetacypermethrin and 20% Piperonyl Butoxide was weighed and attached to collars prior to treatment. Treatment was applied by placing the collars on the dogs' necks with proper fit and ensuring the tags were able to swing freely.

Each untreated control dog had a placebo PVC tag attached to its collar.

Number of replicates per treatment: 6 dogs/ test group.

Number of individuals per replicate: Approximately 50 Brown Dog ticks (*Rhipicephalus sanguineus*), 50 American Dog ticks (*Dermacentor variabilis*); and 100 Cat fleas (*Ctenocephalides felis*) per dog.

Length of exposure to treatment (time in seconds, minutes or hours): Ticks and fleas were removed approximately 48 hours and 24 hours after infestation, respectively; as noted above, reinfestations occurred up to 131 days.

Were tested specimens transferred to clean containers? Not applicable

Experimental conditions (state relative humidity, temperature, and photoperiod):
From Day -7 to Day 145, dogs were housed in indoor pens in an environmentally controlled building.

Data or endpoints collected/recorded: Ticks and fleas were counted and removed on specified days.

Data analysis: Flea and tick counts and percent reduction on dogs were tabulated. Effectiveness was determined by comparing the number of parasites on treated animals to numbers present on the control dogs. A modified Abbott's formula was used to calculate the percent efficacy of treatments:

$$\% \text{ efficacy} = \frac{(\text{\# parasites control}) - \text{\# parasites treated}}{\text{\# parasites control}} \times 100$$

RESULTS

Raw data were not included but are retained and archived at Y-TEX Corporation. Although raw data were not included, total flea and tick counts on each specified day were provided in tabular form. A modified Abbott's formula was used to calculate the percent efficacy of treatments.

No significant protocol amendments or deviations were reported.

YT-1601 Dog Tag was effective in controlling Cat fleas starting on Day 2 and continuing up to 119 days, with the percent efficacy ranging from 92% to 100%. Efficacy started to decline on Day 132, with an efficacy of 80%. A summary of the data is presented in the following table.

Table 3. Flea counts and percent reduction on dogs treated with 4-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Summer 2010.

			Flea Counts											
Dog #	Tag Weight (grams)	15 May 10 Day +2	19 May 10 Day +6	26 May 10 Day +13	02 Jun 10 Day +20	16 Jun 10 Day +34	30 Jun 10 Day +48	14 Jul 10 Day +62	28 Jul 10 Day +76	11 Aug 10 Day +90	25 Aug 10 Day +104	09 Sep 10 Day +119*	22 Sep 10 Day +132
0755	4 (blank)	54	53	58	67	71	67	63	68	63	63	65	63
0769	4 (blank)	63	67	61	71	73	71	71	71	76	70	68	61
0427	4 (blank)	61	63	67	63	68	63	69	63	68	61	63	74
0723	4 (blank)	68	51	57	69	67	75	61	74	76	59	68	69
0818	4 (blank)	59	53	51	75	69	69	58	63	67	67	71	73
ZPI-7	4 (blank)	57	49	43	61	59	72	73	78	69	62	66	67
Average		**60.3**	**56.0**	**56.2**	**67.7**	**67.8**	**69.5**	**65.8**	**69.5**	**69.8**	**63.7**	**66.8**	**67.8**
0602	4	9	0	2	0	0	0	0	0	0	2	0	1
0813	4	2	0	0	0	0	0	0	0	0	1	0	2
0823	4	1	0	0	0	0	0	0	0	0	2	3	14
0772	4	6	0	0	0	0	0	0	2	0	5	7	22
0606	4	2	0	0	0	0	0	0	1	5	5	0	14
0768	4	9	0	0	0	0	0	1	7	4	14	7	28
Average		**4.8**	**0.0**	**0.3**	**0.0**	**0.0**	**0.0**	**0.2**	**1.7**	**1.5**	**4.8**	**2.8**	**13.5**
% Control**		**92.0**	**100.0**	**99.4**	**100.0**	**100.0**	**100.0**	**99.7**	**97.6**	**97.9**	**92.4**	**95.8**	**80.1**

*Count done on Day +119 rather than +118 as allowed by protocol.

**% control calculated by modified Abbott's formula: % efficacy = $\frac{(\#\text{ control} - \#\text{ treated})}{\#\text{ control}}$ X 100

YT-1601 Dog Tag was variable in its effectiveness in controlling the American Dog tick. The percent efficacy was 63 and 84% on Days 2 and 6, increasing to a maximal effectiveness of 99% on Day 13. The percent effectiveness then ranged from 69 to 88% up to Day 119. A summary of the data is presented in the following table.

Table 4. Tick counts and percent reduction for *Dermacentor variabilis* on dogs treated with 4-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Summer 2010.

			Tick Counts, *Dermacentor variabilis*											
Dog #	Tag Weight (grams)	10 May 10 Day -3	15 May 10 Day +2	19 May 10 Day +6	26 May 10 Day +13	02 Jun 10 Day +20	16 Jun 10 Day +34	30 Jun 10 Day +48	14 Jul 10 Day +62	28 Jul 10 Day +76	11 Aug 10 Day +90	25 Aug 10 Day +104	09 Sep 10 Day +119**
0755	4 (blank)	*	28	20	19	19	21	19	17	19	18	19	17
0769	4 (blank)	*	30	17	21	23	19	21	19	24	23	21	19
0427	4 (blank)	*	38	19	23	17	24	16	14	17	19	17	18
0723	4 (blank)	*	22	16	18	18	17	23	18	23	21	23	17
0818	4 (blank)	*	33	17	21	19	19	18	21	24	21	17	19
ZPL7	4 (blank)	*	24	21	19	21	18	23	19	18	19	21	20
Average			**29.2**	**18.3**	**20.2**	**19.5**	**19.7**	**20.0**	**18.0**	**20.8**	**20.2**	**19.7**	**18.3**
0602	4	*	26	4	0	0	1	0	1	1	0	0	0
0813	4	*	6	5	0	0	0	0	8	6	5	7	5
0823	4	*	5	0	0	4	1	4	1	2	1	1	1
0772	4	*	7	6	1	13	8	16	19	8	16	16	18
0606	4	*	12	0	0	0	0	1	4	5	6	4	2
0768	4	*	9	3	0	0	4	3	1	4	2	3	1
Average			**10.8**	**3.0**	**0.2**	**2.8**	**2.3**	**4.0**	**5.7**	**4.3**	**5.0**	**4.8**	**4.4**
% Control* **			**62.9**	**83.6**	**99.2**	**85.5**	**88.1**	**80.0**	**68.5**	**79.2**	**75.2**	**75.6**	**76.0**

*D. v. ticks were not used for the pre-treatment count.

**Count done on Day +119 rather than +118 as allowed by protocol.

***% control calculated by modified Abbott's formula: % efficacy = $\frac{(\text{\# control} - \text{\# treated})}{\text{\# control}}$ X 100

YT-1601 Dog Tag was also variable in its effectiveness in controlling the Brown Dog tick. The percent efficacy was 63% on Day 2, increasing to 91 and 97% on Day 6 and 13, respectively. Thereafter the percent effectiveness ranged 86 to 93% up to Day 104, decreasing to 73% on Day 119. A summary of the data is presented in the following table.

Table 5. Tick counts and percent reduction for *Rhipicephalus sanguineus* on dogs treated with 4-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Summer 2010.

			Tick Counts, *Rhipicephalus sanguineus*											
Dog #	Tag Weight (grams)	10 May 10 Day -3	15 May 10 Day +2	19 May 10 Day +6	26 May 10 Day +13	02 Jun 10 Day +20	16 Jun 10 Day +34	30 Jun 10 Day +48	14 Jul 10 Day +62	28 Jul 10 Day +76	11 Aug 10 Day +90	25 Aug 10 Day +104	09 Sep 10 Day +119*
0755	4 (blank)	29	32	23	24	21	24	25	21	21	25	21	23
0769	4 (blank)	27	29	21	23	17	21	25	25	27	29	17	20
0427	4 (blank)	29	41	26	17	20	23	21	23	23	25	23	25
0723	4 (blank)	17	28	19	23	21	25	19	26	29	31	19	21
0838	4 (blank)	15	40	23	19	23	23	26	23	31	27	20	24
ZP1-7	4 (blank)	26	27	18	21	25	21	29	25	24	21	24	23
Average		**23.8**	**32.8**	**21.7**	**21.2**	**21.2**	**22.8**	**23.8**	**23.8**	**25.8**	**26.3**	**20.7**	**22.7**
0502	4	23	14	0	0	0	0	0	0	0	0	0	0
0813	4	23	24	1	0	0	0	0	9	0	0	1	7
0823	4	19	11	0	0	1	1	0	0	1	0	0	1
0772	4	28	9	8	4	14	9	11	10	7	15	13	15
0606	4	35	13	2	0	0	0	0	0	0	1	0	14
0768	4	21	2	1	0	2	0	1	0	4	0	2	1
Average		**24.8**	**12.2**	**2.0**	**0.7**	**2.8**	**1.7**	**2.0**	**3.2**	**2.0**	**3.2**	**3.0**	**6.2**
% Control**			**62.9**	**90.8**	**96.9**	**86.6**	**92.7**	**91.6**	**86.7**	**92.3**	**87.8**	**85.5**	**72.6**

*Count done on Day +119 rather than +118 as allowed by protocol.

**% control calculated by modified Abbott's formula: % efficacy = $\frac{(\text{\# control} - \text{\# treated})}{\text{\# control}}$ X 100

Study Author's Conclusions

The 4 gram tag was especially efficacious against cat fleas on beagles for about 4.5 months. Although not quite as pronounced, the tag was good to excellent against Brown Dog ticks. The tag also aided significantly in suppressing American Dog tick infestations on beagles. In general, the tag served as a very good deterrent against fleas and Brown Dog ticks for about 4 months and offered considerable aid against American Dog ticks on beagle dogs.

Reviewer's Conclusions

1. All dogs survived to study termination, and no adverse effects related to treatment were observed.

2. The percent efficacy of the product was calculated using a modified Abbott's Formula. Efficacy of YT-1601 Dog Tags was acceptable against Cat fleas, ranging from 92-100% over Days 2 to 119.

3. YT-1601 Dog Tag was considered effective in controlling the Brown Dog tick (*Rhipicephalus sanguineus*). Of the 11 measured time points, 5 showed efficacy of at least 90% (occurring between days 6 and 76), while 4 showed efficacies between 80-90%. Only the first and last measured time point (Day 2 and Day 119) had a low percent efficacy of 63 and 73%, respectively. The OCSPP 810.3300 Guidelines concerning control of ticks state that "in general, 90% control is a desirable level of reduction, but even 80% control may support label claim under certain circumstances."

4. YT-1601 Dog Tag was considered effective in aiding in control of the American Dog tick (*Dermacentor variabilis*). Only one time point showed an efficacy of at least 90% (Day 13 at 99%). The percent effectiveness for other time points ranged from 63 to 88% up to Day 119.

Reviewer's Recommendations

1. The study is acceptable. No study deficiencies were noted.

2. The study supports the addition of fleas to the product label; the data support the claim "Controls fleas for up to 4 months."

3. The study does not support the addition of Brown Dog ticks to the product label as currently specified; the data do not support the claim "Controls Brown Dog ticks for up to 4 months" for "application to dogs weighing 14-29 pounds (4 gram medallion label)" because efficacy was demonstrated only up to 104 days, or 3.5 months. However, the data would support the claim if "up to 4 months" were changed to "up to 3 months."

4. The study supports the addition of American Dog ticks to the product label; the data support the claim "Aids in control of American Dog ticks for up to 4 months" for "application to dogs weighing 14-29 pounds (4 gram medallion label)."

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 486097-01. Hair, J.A. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. June 21, 2010.

OCSPP 810.3300. Treatments to Control Pests of Humans and Pets

Product Name: YT-1601 Dog Tag
EPA Reg. No. or File Symbol: 39039-14
Decision number: 455575
DP number: 395185

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-53

Primary Reviewer:
Claudia Troxel, Ph.D.

Signature: Claudia M. Troxel
Date: JAN 25 2012

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature:
Date: JAN 25 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: JAN 25 2012

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JAN 25 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3300]
MRID:	486097-01. The Efficacy of Insecticide Dog Tag Formulations for the Control of Fleas and Ticks Infesting Dogs. Hair, J.A. 2010.
DP BARCODE:	395185
DECISION NO:	455575
SUBMISSION NO:	904194
SPONSOR:	Y-TEX Corporation, 1825 Big Horn Ave, Cody, WY 82414
TESTING FACILITY:	Nu-Era Farms, 320 N. Range Rd., Stillwater, OK 74075
STUDY DIRECTOR:	J. Alexander Hair, Ph.D.
SUBMITTER:	Joe D. Kellerby, M.S., P.E., Vice President – Specialty Products, Y-TEX Corporation
STUDY COMPLETED:	12/04/2010
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	"Although this study was not conducted to GLP requirements of 40 CFR Part 160, good scientific practices were followed throughout."
TEST MATERIAL: [As noted on label]	PRODUCT NAME: YT-1601 Dog Tag EPA REGISTRATION NUMBER OR FILE SYMBOL: 39039-14 ACTIVE INGREDIENT NAME: Zetacypermethrin, S-enantiomer CHEMICAL NAME: S-Cyano(3-phenoxyphenyl)methyl (+-)cis/trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-carboxylate A.I. %: 10% PC CODE: 129064

	CAS NO.: 52315-07-8 ACTIVE INGREDIENT NAME: Piperonyl butoxide CHEMICAL NAME: (butylcarbityl)(6-propylpiperonyl)ether A.I. %: 20% PC CODE: 067501 CAS NO.: 51-03-6 FORMULATION TYPE: Collar attached medallion PRODUCT APPLICATION RATE(S) g/m^2: ACTIVE INGREDIENT APPLICATION RATE(S)g/m^2:
PROPOSED LABEL MARKETING CLAIMS:	Controls fleas for up to four months, Controls Brown Dog ticks for up to four months, aids in control of American Dog ticks for up to four months, for application to dogs weighting over 55 pounds (8 g medallion label)

STUDY REVIEW

Purpose: The objectives of this study were to determine the efficacy of candidate insecticide dog tag formulations for control of fleas and ticks infesting dogs, to determine the residual protection achieved from the treatments for tick control over time, and to determine whether any adverse reactions occurred from the treatments.

MATERIALS AND METHODS

Test Location Nu-Era Farms, Stillwater, OK.

Test Material(s): YT-1601-M5 comprised of Zetacypermethrin (10%) and Piperonyl Butoxide Tech. (20%) in a 8-gram tag on a collar; equivalent to label rate.

Test Species Name, Life Stage, Sex and Age: Adult Brown Dog Ticks (*Rhipicephalus sanguineus*), adult American Dog Ticks (*Dermacentor variabilis*), and adult Cat Fleas (*Ctenocephalides felis*).

Experimental animal: dog (*Canis familiaris*); mixed hound and purebred greyhound; 1-8 years, 9 males and 3 females; 29.60 to 52.30 kg.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Dogs were housed in indoor pens approximately 6 x 10 x 6 feet high with welded wire walls and concrete floors. After allocation, dogs were grouped by treatment and different treatment groups were separated by physical space. Dogs were infested with approximately 50 Brown Dog ticks on Day -5 to determine that the dogs were suitable hosts. These ticks were counted and removed on Day -3, approximately 48 hours after infestation. It was determined that the dogs were suitable parasite hosts for the trial.

Fleas were infested onto the dog by placing the open top of a container with a known number of fleas on the flank of the animals and holding the container in place until the parasites entered the hair coat. Flea infestation was evaluated at approximately 24 hours post challenge as outlined in the Schedule of Operations. The hair coat was examined in a methodical manner to count fleas on all portions of the dog including the tail and legs. Fleas were combed from the dogs and counted and disposed of.

Ticks were infested onto the dogs by scattering the ticks onto the hair coat of the dog taking care to avoid the site of treatment and to avoid having a large number of ticks attach in a small area. Ticks were removed and counted on all dogs at approximately 48 hours after challenge as per the Schedule of Operations, with the exception of the tick counts on Days +2 which was approximately 72 hours after challenge due to treatment. Tick counts were performed by pushing the animal's hair against its natural nap so that the skin and any ticks were exposed during the process. All areas of the animals were systematically examined and ticks removed with blunt-point forceps and placed in a dish of alcohol for counting.

Dogs were infested with approximately 50 of each type of tick on Days -1, 4, 7, 11, 20, 32, 46, 60, 74, 88, 102, 116, 130, 144, 158 and 172, and were infested with approximately 100 Cat fleas on Days 1, 5, 12, 21, 33, 47, 61, 75, 89, 103, 117, 131, 145, 159, and 173. Fleas and ticks were counted and removed on Days 2, 6, 9 (ticks only), 13, 22, 34, 48, 62, 76, 90, 104, 118, 132, 146, 160, and 174.

List the treatments including untreated control (express application rate as g/m^2):
The 8-gram tag containing 10% Zetacypermethrin and 20% Piperonyl Butoxide was weighed and attached to collars prior to treatment. Treatment was applied by placing the collars on the dogs' necks with proper fit and ensuring the tags were able to swing freely.

Each untreated control dog had a placebo PVC tag attached to its collar.

Number of replicates per treatment: 6 dogs/ test group

Number of individuals per replicate: approximately 50 Brown dog ticks (*Rhipicephalus sanguineus*), 50 American dog ticks (*Dermacentor variabilis*); and 100 Cat fleas (*Ctenocephalides felis*) per dog

Length of exposure to treatment (time in seconds, minutes or hours): Ticks and fleas were removed approximately 48 hours and 24 hours after infestation, respectively; reinfestations occurred up to 173 days.

Were tested specimens transferred to clean containers? not applicable

Experimental conditions (state relative humidity, temperature, and photoperiod):
From Day -7 to Day 179, dogs were housed in indoor pens in an environmentally controlled building.

Data or endpoints collected/recorded: ticks and fleas were counted and removed on specified days

Data analysis: Flea and tick counts and percent reduction on dogs were tabulated. Effectiveness was determined by comparing the number of parasites on treated animals to numbers present on the control dogs. A modified Abbott's formula was used to calculate the percent efficacy of treatments:

$$\% \text{ efficacy} = \frac{(\#\text{ parasites control}) - \#\text{ parasites treated})}{\#\text{ parasites control}} \times 100$$

RESULTS

Raw data were not included but are retained and archived at Y-TEX Corporation. Although raw data were not included, total flea and tick counts on each specified day were provided in tabular form. A modified Abbott's formula was used to calculate the percent efficacy of treatments.

The protocol was amended to add an additional tick infestation on Day 7 because an additional data point was desired for ticks.

YT-1601-M5 Dog Tag was effective in controlling Cat fleas starting on Day 2 and continuing up to 146 days, with the percent efficacy ranging from 94.6% to 100%. Efficacy started to decline on Days 160 and 174, with a percent efficacy of 88 and 86% respectively. A summary of the data is presented in the following table.

Table 4. Flea counts and percent reduction on dogs treated with 8-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Fall 2009.

		Flea Counts														
Dog #	Tag Weight (grams)	17 Oct 09 Day +2	21 Oct 09 Day +6	28 Oct 09 Day +13	06 Nov 09 Day +22	18 Nov 09 Day +34	02 Dec 09 Day +48	16 Dec 09 Day +62	30 Dec 09 Day +76	13 Jan 10 Day +90	27 Jan 10 Day +104	10 Feb 10 Day +118	24 Feb 10 Day +132	10 Mar 10 Day +146	24 Mar 10 Day +160	07 Apr 10 Day +174
18D	8 (blank)	65	71	78	55	51	67	70	74	77	69	73	71	73	69	67
2307	8 (blank)	53	67	71	68	70	71	69	72	71	73	77	78	79	73	63
2202	8 (blank)	69	63	69	40	69	73	72	73	75	63	66	61	64	67	71
2001	8 (blank)	79	76	86	71	51	63	68	76	77	74	71	69	72	70	61
2210	8 (blank)	67	84	94	83	92	83	81	83	80	67	70	73	74	68	73
127G	8 (blank)	57	55	61	59	62	65	67	70	69	71	72	67	71	74	76
Average		**65.0**	**69.3**	**76.5**	**62.7**	**65.8**	**70.3**	**71.2**	**74.7**	**74.8**	**69.5**	**71.5**	**69.8**	**72.2**	**70.2**	**68.5**
131G	8	2	3	0	0	0	0	1	0	0	0	3	6	0	22	29
310	8	2	2	0	0	0	0	0	0	*	0	0	1	0	2	8
18A	8	5	9	9	0	1	0	0	0	3	9	4	3	5	19	13
2298	8	11	0	0	0	0	0	0	0	0	1	1	1	8	8	9
2265	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2327	8	1	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Average		**3.5**	**2.3**	**1.5**	**0.0**	**0.2**	**0.0**	**0.2**	**0.0**	**0.6**	**1.7**	**1.5**	**1.8**	**2.3**	**8.5**	**9.8**
% Control**		**94.6**	**96.6**	**98.0**	**100.0**	**99.7**	**100.0**	**99.8**	**100.0**	**99.2**	**97.6**	**97.9**	**97.4**	**96.8**	**87.9**	**85.6**

*Dog 310 not infested due to broken tail.

**% control calculated by modified Abbott's formula: $\%\ \text{efficacy} = \frac{(\#\ \text{control} - \#\ \text{treated})}{\#\ \text{control}} \times 100$

YT-1601-M5 Dog Tag was variable in its effectiveness in controlling the American Dog tick. The percent efficacy was 75 and 78% on Days 2 and 6, increasing to 91 and 87% Days 9 and 13. Maximal effectiveness was seen on Day 22 at 99%, after which the percent effectiveness ranged from 72 to 88% up to Day 132. Thereafter, the percent efficacy dropped to 59, 55, and 41%. A summary of the data is presented in the following table.

Table 5. Tick counts and percent reduction for *Dermacentor variabilis* on dogs treated with 8-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Fall 2009.

		Tick Counts, *Dermacentor variabilis*																
Dog #	Tag Weight (g)	12 Oct 09 Day -3	17 Oct 09 Day +2	21 Oct 09 Day +6	24 Oct 09 Day +9	28 Oct 09 Day +13	06 Nov 09 Day +22	18 Nov 09 Day +34	02 Dec 09 Day +48	16 Dec 09 Day +62	30 Dec 09 Day +76	13 Jan 10 Day +90	27 Jan 10 Day +104	10 Feb 10 Day +118	24 Feb 10 Day +132	10 Mar 10 Day +146	24 Mar 10 Day +160	07 Apr 10 Day +174
18D	8 (blank)	*	34	23	24	25	19	28	35	34	36	32	28	32	30	26	23	19
2307	8 (blank)	*	27	22	21	27	21	25	29	39	38	34	26	31	29	25	21	24
2202	8 (blank)	*	21	24	26	21	23	38	32	23	26	28	23	24	19	17	20	18
2001	8 (blank)	*	33	28	25	27	29	21	11	17	22	25	21	25	23	22	23	24
2210	8 (blank)	*	23	29	27	23	28	28	27	30	31	26	19	21	19	23	18	23
127G	8 (blank)	*	21	13	19	19	31	22	18	23	20	24	21	19	18	16	18	20
Average			**26.5**	**23.2**	**23.7**	**23.7**	**25.2**	**27.0**	**25.3**	**27.7**	**28.8**	**28.2**	**23.0**	**25.3**	**23.0**	**21.5**	**20.5**	**21.3**
131G	8	*	3	0	1	0	0	3	0	2	1	0	0	5	0	2	11	14
310	8	*	3	1	0	0	1	2	0	1	0	**	1	0	1	11	8	13
18A	8	*	10	18	7	11	0	7	7	8	11	3	4	4	6	7	5	7
2298	8	*	8	3	3	5	0	6	5	7	3	3	5	3	2	8	10	14
2265	8	*	0	4	1	3	0	9	4	20	26	16	7	8	12	15	12	16
2327	8	*	16	5	1	0	0	6	3	8	7	6	6	8	10	10	10	12
Average			**6.7**	**5.2**	**2.2**	**3.2**	**0.2**	**5.5**	**3.2**	**7.7**	**8.0**	**5.6**	**3.8**	**4.7**	**5.2**	**8.8**	**9.3**	**12.7**
% Control***			**74.8**	**77.7**	**90.8**	**86.6**	**99.3**	**79.6**	**87.5**	**72.3**	**72.3**	**80.1**	**83.3**	**81.6**	**77.5**	**58.9**	**54.5**	**40.6**

**D.v.* ticks were not used for the pre-treatment count.

***Dog 310 not infested due to broken tail.

****% control calculated by modified Abbott's formula: $\%\ \text{efficacy} = \frac{(\#\ \text{control} - \#\ \text{treated})}{\#\ \text{control}} \times 100$

YT-1601-M5 Dog Tag was variable in its effectiveness in controlling the Brown Dog tick. The percent efficacy was 68, 81, 89, and 84% on Days 2, 6, 9 and 13, respectively, increasing to 96% Day 22. Thereafter the percent effectiveness ranged 86.0 to 98% up to Day 146. A summary of the data is presented in the following table.

Table 6. Tick counts and percent reduction for *Rhipicephalus sanguineus* on dogs treated with 8-gram 10% Zetacypermethrin and 20% PBO Tech., Nu-Era Farms, Stillwater, OK 74075, Fall 2009.

		Tick Counts, *Rhipicephalus sanguineus*																
Dog #	Tag Weight (grams)	12 Oct 09 Day -3	17 Oct 09 Day +2	21 Oct 09 Day +6	24 Oct 09 Day +9	28 Oct 09 Day +13	06 Nov 09 Day +22	18 Nov 09 Day +34	02 Dec 09 Day +48	16 Dec 09 Day +62	30 Dec 09 Day +76	13 Jan 10 Day +90	27 Jan 10 Day +104	10 Feb 10 Day +118	24 Feb 10 Day +132	10 Mar 10 Day +146	24 Mar 10 Day +160	07 Apr 10 Day +174
18D	8 (blank)	22	40	34	29	19	22	21	23	27	29	25	25	19	23	27	25	21
2307	8 (blank)	29	19	27	23	22	13	19	21	22	26	31	21	15	18	19	23	19
2202	8 (blank)	22	18	21	19	18	18	26	18	15	18	23	17	20	21	22	19	23
2001	8 (blank)	19	29	23	21	21	23	18	16	19	29	31	27	26	19	23	25	18
2210	8 (blank)	26	16	26	21	26	26	31	14	15	19	21	23	20	16	19	21	21
127G	8 (blank)	31	17	24	23	16	28	24	23	31	30	28	27	29	22	21	23	25
Average		**24.8**	**23.2**	**25.8**	**22.7**	**20.3**	**21.7**	**23.2**	**19.2**	**21.5**	**25.2**	**26.5**	**23.3**	**21.5**	**19.8**	**21.8**	**22.7**	**21.2**
131G	8	25	2	1	1	4	1	1	0	4	0	0	4	0	0	0	4	3
310	8	23	3	3	2	1	0	3	0	3	0	*	0	7	4	6	7	6
18A	8	18	21	16	9	10	1	0	0	8	14	0	3	1	0	0	2	1
2298	8	26	5	1	0	1	2	0	0	0	0	0	0	0	1	1	3	2
2265	8	20	0	7	3	3	1	5	0	2	4	1	1	3	3	3	5	1
2327	8	30	14	2	0	0	0	2	3	1	0	2	5	0	2	4	6	1
Average		**23.7**	**7.5**	**5.0**	**2.5**	**3.2**	**0.8**	**1.8**	**0.5**	**3.0**	**3.0**	**0.6**	**2.2**	**1.8**	**1.7**	**2.3**	**4.5**	**2.3**
% Control**			**67.6**	**80.6**	**89.0**	**84.4**	**96.2**	**92.1**	**97.4**	**86.0**	**88.1**	**97.7**	**90.7**	**91.5**	**91.6**	**89.3**	**80.1**	**89.0**

*Dog 310 not infested due to broken tail.

**% control calculated by modified Abbott's formula: $\%\ \text{efficacy} = \frac{(\#\ \text{control} - \#\ \text{treated})}{\#\ \text{control}} \times 100$

Study Author's Conclusions

On Day +2 following treatment with 8-gram tags flea numbers on treated dogs had decreased by 95% and Brown Dog tick numbers were reduced by 90% by day +9 post treatment and excellent control was seen for 146 days. Ninety-one percent of American dog ticks were killed by Day +9 and fair to good control was seen for 132 days post treatment. The tag was especially efficacious against cat fleas on large dogs for about 5 months. Although not quite as pronounced, the tag was good to excellent against brown dog ticks considering the body area to be treated on the very large study dogs. The tag also aided significantly in suppressing American dog ticks infestations on hounds.

Reviewer's Conclusions

1. All dogs survived to study termination, and no adverse effects related to treatment were observed.

2. The percent efficacy of the product was calculated using a modified Abbott's Formula.

3. Efficacy of YT-1601-M5 Dog Tags was acceptable against Cat fleas, ranging from 95-100% over Days 2 to 146.

4. YT-1601-M5 Dog Tag was considered effective in controlling the Brown Dog tick (*Rhipicephalus sanguineus*). Of the 16 measured time points, 7 showed efficacy of at least 90% (occurring between days 22 and 132), while 8 showed efficacies between 80-90% (3 occurring over Days 2 to 9 and 3 on days 146 to 174). Only the first measured time point of Day 2 had a low percent efficacy of 68%. The OCSPP 810.3300 Guidelines concerning control of ticks state that "in general, 90% control is a desirable level of reduction, but even 80% control may support label claim under certain circumstances."

5. YT-1601-M5 Dog Tag was considered effective in aiding in control of the American Dog tick (*Dermacentor variabilis*). Only two time points showed an efficacy of at least 90% (Day 9 and 22). The percent efficacy at remaining time points up to 132 days ranged from 72 and 88%. Efficacy was less than 59% at remaining time points.

Reviewer's Recommendations

1. The study is acceptable. No study deficiencies were noted.

2. The study supports the addition of fleas to the product label; the data support the claim "Controls fleas for up to 4 months" for "application to dogs weighing over 55 pounds (8 gram medallion label)."

3. The study supports the addition of Brown Dog ticks to the product label; the data support the claim "Controls Brown Dog ticks for up to 4 months" for "application to dogs weighing over 55 pounds (8 gram medallion label)."

4. The study supports the addition of American Dog ticks to the product label; the data support the claim "Aids in control of American Dog ticks for up to 4 months" for "application to dogs weighing over 55 pounds (8 gram medallion label)."